In re Baxter Travenol Labs (CA FC) 21 USPQ2d 1281

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U.S. Court of Appeals Federal Circuit
21 USPQ2d 1281

Decided December 30, 1991
No. 91-1313

Headnotes

PATENTS

1. Patentability/Validity - Anticipation - In general (§ 115.0701)

JUDICIAL PRACTICE AND PROCEDURE

Procedure - Judicial review - Standard of review - Patents (§ 410.4607.09)

Anticipation is question of fact, and finding by Board of Patent Appeals and Interferences that invention is anticipated will therefore not be reversed unless it is clearly erroneous.

PATENTS

2. Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)

Blood collection and storage system employing first or donor bag containing hemolysis-suppressing plasticizer di-2-ethylhexyl pthalate (DEHP) and second bag made from plastic polymer free of blood leachable plasticizer is obvious in view of blood bag system described in prior art document, since that system is described as being "very similar" to re-examination applicant's then-existing commercial system except for its use of second bag made from Teflonâ, since testimony and applicant's own admissions show that applicant's commercial systems all utilized DEHP-plasticized primary bag at that time, and since one skilled in art would therefore have known that document refers to DEHP-plasticized primary bag.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Depositions and declarations of skilled workers, re-examination applicant's admissions, and testimony given by author of prior art reference in earlier interference proceeding were properly considered in determining anticipatory teaching of that reference, since extrinsic evidence may be considered when it is used to explain meaning of reference, although it cannot be used to expand such meaning, and in present case evidence in question was used to explain meaning of particular phrase in prior reference.

4. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)

Fact that blood collection and storage system described in prior art reference was experimental and lacked Food and Drug Administration approval is irrelevant to issue of anticipation, since person of ordinary skill in art would recognize all elements of claimed invention in system described by reference even without knowledge of that fact.

5. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Application claims that are anticipated by prior art reference are also obvious in view of that reference under 35 USC 103.

6. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Re-examination applicant has not shown that Board of Patent Appeals and Interferences erred by finding claims obvious, since applicant, rather than arguing merits of any specific claim demonstrating non-obviousness, asserts general premise that particular prior art reference would not have suggested particular element of invention, and since reference has been shown to teach use of that element.

7. Patentability/Validity - Obviousness - Commercial success (§ 115.0908)

Re-examination applicant's assertion that commercial success of invention rebuts prima facie finding of obviousness is unpersuasive, since applicant has not effectively argued that particular claims in question differ from what is disclosed in prior art reference, and since applicant's evidence concerning number of units sold, submitted without market share information, is insufficient to establish commercial success.

8. Patentability/Validity - Obviousness - Secondary considerations generally (§ 115.0907)

Re-examination applicant's assertion that unexpected hemolysis-suppression quality of plasticizer used in donor bag of blood collection system rebuts prima facie showing of obviousness is unpersuasive, since results must be unexpected as compared to closest prior art in order to qualify as evidence of non-obviousness, and since closest prior art in present case employed donor bag made with plasticizer in question, although hemolysis-suppressing function of plasticizer was unknown at that time; inventor's mere recognition of latent property in plasticizer did not render otherwise known invention non-obvious.

Particular patents - General and mechanical - Blood bags

4,222,379, Smith, multiple blood bag having plasticizer-free portions and a high blood component survival rate, rejection of claims 1-24 and 29-37 on application for re-examination affirmed.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of Baxter International Inc. for re-examination of patent no. 4,222,379, issued September 16, 1980. From decision upholding rejection of claims 1-24 and 29-37, applicant appeals. Affirmed.

Attorneys:
Daniel D. Ryan, of Fuller, Ryan & Hohenfeldt, Milwaukee, Wis. (Bradford R.L. Price, Deerfield, Ill., of counsel), for Baxter Travenol Labs.

Teddy S. Gron (Fred E. McKelvey, solicitor, and Richard E. Schafer, associate solicitor, with him on brief), for Commissioner of Patents and Trademarks.

Judge:
Before Nies, chief judge, and Plager and Lourie, circuit judges.

Opinion Text

Opinion By:
Lourie, J.

Baxter International, Inc. (Baxter) appeals from the February 28, 1991, decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, Appeal No. 90-2204. The Board affirmed the rejection of claims 1, 3-12, 14-16, 20-23, and 29-37, in a reexamination of U.S. Patent 4,222,379 (the Smith patent) as anticipated under 35 U.S.C. §102(b). The Board also affirmed the rejection of claims 1-24 as obvious under 35 U.S.C. §103. Claims 25-28 were allowed by the examiner and are not in issue. We affirm.

BACKGROUND

The Smith invention relates to a multiple blood bag system for collecting, processing and storing the therapeutic components of whole blood (red blood cells, plasma, and platelets). 1 The system includes a first (donor) bag for collection and storage of the red blood cells and at least one second (transfer) bag 2 for collection and storage of another blood component. According to the Smith invention, the donor bag contains a hemolysis-suppressing, blood-leachable plasticizer, di-2-ethylhexyl phthalate (DEHP), whereas the second bag is made of a different plastic polymer, free of blood leachable plasticizer. Prior to the time of the Smith invention, the industry used DEHP as a plasticizer in blood storage bags, but desired to eliminate DEHP due to concern about its possible deleterious effects. It was discovered by another Baxter employee that DEHP had the apparently unexpected effect of suppressing hemolysis in red blood cells, thus making it desirable to store red blood cells in bags containing DEHP. The Smith patent claimed this discovery as a multiple bag system.

On October 16, 1987, Baxter filed a request for reexamination of the Smith patent. With the request, Baxter submitted a copy of a document entitled "Contract PH 43-67-1403; Final Technical Progress Report; Development of Containers for Preservation of Frozen Blood Components" (Becker document). This document, describing a new blood bag system, was authored by Mr. Becker, a Baxter employee, in October 1969 and was discovered during preparation for an earlier interference proceeding. Mr. Becker's testimony, taken during the earlier proceeding, was also submitted. In reexamination, the examiner rejected most of the patent claims over the Becker reference and the Board affirmed. Baxter then appealed to this court.

DISCUSSION

A. Anticipation

[1] Anticipation is a question of fact. Therefore, we will not reverse the Board's finding of anticipation unless it is clearly erroneous. *In re Bond,* 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). The Board found that the Becker document taught both two- and three-blood bag systems in which the primary or donor bag

was made of polyvinyl chloride (PVC) and a secondary or satellite bag was made of unplasticized Teflon®. The Board also found that one skilled in the art would have known that the primary bag was plasticized with DEHP, thereby anticipating the Smith invention. We agree.

[2] In describing its blood bag system, the Becker document makes two references to then-available commercial blood bag systems. The most significant reference is on page 49, where Becker describes his double blood pack system design as "very similar to [Baxter] Travenol's commercial, two bag blood container. The exception is that the secondary transfer pack was a 350 ml Teflon container. ..." The Board was correct in characterizing the dispositive question regarding anticipation as whether one skilled in the art would reasonably understand or infer from the Becker document's teaching that Becker's primary bag was plasticized with DEHP. As Baxter notes, there is no express reference to DEHP in the Becker document.

Testimony from those skilled in the art, through depositions and declarations, and Baxter's own admissions, established that Baxter's commercial systems during this time period all contained a primary bag plasticized with DEHP. Therefore, since Becker referred to Baxter's commercial system and Baxter's commercial systems utilized a DEHP-plasticized primary bag, it is clear that one skilled in the art would have known that Becker was referring to a DEHP-plasticized primary bag. That fact, coupled with Becker's disclosure that the second bag was made of Teflon®, leads to the unmistakable conclusion that the claims at issue were anticipated.

[3] Baxter argues that these depositions, declarations, and admissions are extrinsic evidence, which may not be considered when determining the anticipatory teaching of a reference. This is incorrect. Baxter acknowledges, as it must, that extrinsic evidence may be considered when it is used to explain, but not

expand, the meaning of a reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576-77, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Here, the depositions and declarations of skilled workers and Baxter's admissions were used to identify what materials Baxter's commercial bags contained at the time of the Becker document, thereby explaining what the phrase "[Baxter] Travenol's commercial, two blood bag container" would have meant to one skilled in the art. This evidence clearly shows that those skilled in the art, reading the Becker document, would have known that Becker's primary bag was plasticized with DEHP.

Additionally, Becker testified during the earlier interference that the primary bag in "[Baxter] Travenol's commercial, two bag blood container," to which he referred, contained DEHP. Baxter argues that this too is improperly considered extrinsic evidence and that we must look only at what the Becker document said, not at what Becker himself did. This, however, is precisely what the Board did in considering the testimony. Becker's testimony merely explained what he meant when using the phrase, "[Baxter] Travenol's commercial, two blood bag container." Although Baxter in its briefs to us questions the propriety of using Becker's testimony, the Board's decision did not depend solely upon it, nor does ours.

[4] Baxter further argues that the Becker system was experimental, not FDA approved. Therefore, one skilled in the art would not necessarily have thought that Becker's primary bag must have been plasticized with the only FDA approved plasticizer (DEHP), since there were other non-DEHP (non-FDA approved) plasticizers available at that time. This argument is not persuasive. The fact that Becker's system was experimental is irrelevant. Becker taught use of the primary bag from Baxter's commercial system, which was plasticized with DEHP. Therefore, all the elements of the Smith claims were disclosed in the Becker document and that is sufficient for anticipation. Neither the fact that FDA approval was not needed nor the availability of other materials affects the result, since the evidence showed that the Becker reference disclosed the claimed invention, including a donor bag plasticized with DEHP.

The Board therefore properly concluded that one skilled in the art would have known that Becker was referring to a DEHP-plasticized primary bag and a Teflon® secondary bag, a combination within the scope of the appealed claims. Since we do not find the Board's conclusion to be clearly erroneous, we affirm its finding that claims 1, 3-12, 14-16, 20-23, and 29-37 were anticipated by the Becker document.

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B. Obviousness

[5] The Board affirmed the rejection of claims 1-24 as obvious. Since we have agreed that Becker anticipates the subject matter of claims 1, 3-12, 14-16, 20-23, and 29-37, and

since anticipation is the ultimate of obviousness, *see In re Fracalossi*, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982), the subject matter of these claims is necessarily obvious and we need not consider them further.

As for claims 2, 13, 17-19, and 24, which were rejected only for obviousness, Baxter has conceded that these claims stand or fall together. The Board found that in addition to the express teachings of Becker, the admitted knowledge in the prior art 4 established that it would have been prima facie obvious to plasticize the donor bag with DEHP and to construct the second bag from materials exhibiting different physical characteristics. We affirm on another basis.

[6] Baxter has not argued nonobviousness with any particularity. Instead, its arguments are based on its premise that the Becker document fails to describe a system containing a DEHP primary. Although claims 2, 13, 17-19, and 24 stand rejected solely under § 103, Baxter has not argued the merits of any specific claim demonstrating nonobviousness. Rather, Baxter has rested its argument on the general premise that Becker would not have suggested to one skilled in the art that the primary bag was plasticized with DEHP, essentially the same argument advanced to rebut the anticipation rejection. It is

not the function of this court to examine the claims in greater detail than argued by an appellant, looking for nonobvious distinctions over the prior art. Since we have determined that the Becker document would have taught use of a DEHP-plasticized donor bag, we affirm the rejection of the remaining claims as obvious.

[7] Baxter also argues that commercial success and unexpected results rebut a prima facie finding of obviousness. Since Baxter has not effectively argued that these particular claims differ from what is disclosed in Becker, this argument must fail. Moreover, information solely on numbers of units sold is insufficient to establish commercial success. *See Kansas Jack, Inc. v. Kuhn,* 719 F.2d 1144, 1151, 219 USPQ 857, 861 (Fed. Cir. 1983). The evidence of commercial success cited by Baxter includes only the percentage of *its* blood bag sales accounted for by the Smith system. No market share information was provided beyond saying that the bags were "significantly favored" by users. Baxter's evidence that most of its commercial bags were within the scope of the patent claims is not sufficient to establish commercial success.

[8] Finally, Baxter argues that the unexpected hemolysis-suppression quality of DEHP rebuts any prima facie showing of obviousness. However, when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art. *In re De Blauwe,* 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Here, the closest prior art was the Becker system, utilizing a DEHP primary bag. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Prindle,* 297 F.2d 251, 254, 132 USPQ 282, 283-84 (CCPA 1962). Since the prior art bags plasticized with DEHP were inherently suppressing hemolysis, albeit unknown at the time of the Becker document, this hemolysis-suppressing function is not a basis for rebutting a prima facie finding of obviousness. 5

We have considered Baxter's other arguments and have found them to be unpersuasive.

CONCLUSION

For the foregoing reasons, the decision of the Board is
AFFIRMED.

Footnotes

Footnote 1. Claims 1 and 2 are representative:

. In a multiple blood bag system which comprises a first bag, a second bag, and conduit means providing sealed flow communication between said first bag and second in which said first bag is made of a plastic material which comprises a different polymer entity from that of said second bag, one of said bags being equipped with a blood collection tube, and the polymer entity of the [sic] first bag exhibiting the characteristic of suppressing hemolysis of blood cells on long term storage, whereby the first bag and second bag exhibit differing physical characteristics which are selectively beneficial to their functions.

. The multiple bag blood system of claim 1 in which a second transfer bag is present, being made of a translucent, flexible, sterilizable material which is free of blood-extractable plasticizers and exhibits a higher carbon dioxide diffusion characteristic than the other bags in the system whereby the pH of the platelets stored therein is resistant to reduction.

Footnote 2. Becker, Baxter, the Board, and the claims variously use the terms first, primary, and donor to mean one bag, and second, secondary, satellite, and transfer to mean a second bag. We will use the terms appropriate to the occasion.

Footnote 3. Baxter acknowledges that claims 1, 3-12, 14-16, 20-23, and 29-37 stand or fall together on anticipation grounds.

Footnote 4. The background of the Smith invention teaches that it is old in the art to use a primary bag plasticized with DEHP and that such bags serve extremely well in the storage of blood components.

Footnote 5. The claims before us are apparatus claims, not method claims.

- End of Case -